

REMARKS

With the entry of this Response, Claims 1-3, 10-12, 17-26, and 30-32 are pending in this application, with Claims 17-24 having been previously withdrawn as directed to non-elected subject matter. In this Response, Applicant has canceled Claims 4-9, 13-16, and 27-29 and has amended Claims 1, 3, 10-12, 17, 19, 21-23, and 25-26.

Claim 1 has been amended to recite “skin” rather than “a cell, tissue, or organ.” Support for the amendments to Claim 1 can be found throughout the as-filed Specification and at page 4 (paragraph 23), in Examples 2 and 3, and in Figures 1-6.

Claim 3 has been amended to recite “skin” rather than “cells.” Support for the amendments to Claim 3 can be found throughout the as-filed Specification and at page 4 (paragraph 23), page 6 (paragraph 36), page 7 (paragraphs 37-38), page 22 (paragraph 100), and in Examples 2 and 3.

Claims 10-12 have been amended to recite the “composition” or the “skin” rather than the “cells”. Support for the amendments to Claims 10-12 can be found throughout the as-filed Specification and at page 4 (paragraph 23), page 7 (paragraphs 39-40), page 8 (paragraphs 49-50), page 20 (paragraph 94), and page 24 (paragraph 110).

Claim 17 has been amended to recite “a skin-containing storage solution” rather than a “cell-containing storage solution” and to recite “utilizing the composition of Claim 1” rather than “a solution comprising a glucosaminoglycan.” Support for the amendments to Claim 17 can be found throughout the as-filed Specification and at page 4 (paragraph 23), page 8 (paragraphs 41-42), page 20 (paragraph 94), and page 23 (paragraph 105).

Claims 19, 21, and 22 have been amended to recite “skin” rather than “cells” and to recite the “composition of Claim 1” rather than the “a composition comprising glucosaminoglycan.” Support for the amendments to Claims 19, 21, and 22 can be found throughout the as-filed Specification and at page 4 (paragraph 23), page 7 (paragraphs 39-40), page 8 (paragraphs 43-44), page 9 (paragraphs 51-53), and page 20 (paragraph 94).

Claim 23 has been amended to recite “skin” rather than “cells.” Support for the amendments to Claim 23 can be found throughout the as-filed Specification and at page 4 (paragraph 23), page 8 (paragraphs 45-46), page 23 (paragraph 106), and in Example 3.

Claims 25 and 26 have been amended to recite a kit comprising “the composition of Claim 1.” Support for the amendments to Claims 25 and 26 can be found throughout the as-filed

Specification and at page 4 (paragraph 23), page 8 (paragraphs 47-48) and page 24 (paragraph 110).

Applicant has added new Claims 30-32. Support for new Claims 30-32 can be found throughout the as-filed Specification and at page 2 (paragraph 9), page 4 (paragraph 23), page 24 (paragraph 107), and in Examples 2-3.

Applicant submits that the amendments to the Listing of Claims do not constitute new subject matter.

CLAIM OBJECTIONS

The Office Action objected to Claim 10, stating that “it appears more appropriate that the ‘composition’, instead of ‘cells’ is in the absence of a non-cell penetrating cryoprotectant.” (Office Action, p. 3). Applicant submits that the amendments to Claim 10 render this objection moot. Therefore, Applicant respectfully requests that the Examiner withdraw this objection and allow Claim 10.

CLAIM REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

The Office Action rejected Claims 5, 11-12, and 25-29 under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicant respectfully traverses this rejection to the extent that the rejection applies to the claims as amended. Applicant notes that in this Response, Claims 5, 27, 28, and 29 have been canceled. Applicant submits that the amendments to Claims 11-12 and 25-26 render these rejections moot. Therefore, Applicant respectfully requests that the Examiner withdraw these rejections and allow Claims 11-12 and 25-26.

CLAIM REJECTIONS UNDER 35 U.S.C. § 102

A. GUIENNE

The Office Action rejected Claims 1-3, 5, 7, 10-12, 25-26, and 28 under 35 U.S.C. § 102(b) as being anticipated by Guienne *et al.* (1999) “Effect of Hyaluronic Acid in a Serum Free Maturation Medium on Bovine Embryo Development,” *Theriogenology*, p. 386 (herein “Guienne”). Specifically, the Office Action stated “Guienne *et al.* teach the composition of cells (i.e. blastocysts) in the serum-free medium comprising HA.” (Office Action, p. 5). Applicant

respectfully traverses this rejection to the extent that the rejection applies to the claims as amended. Applicant notes that in this Response, Claims 5, 7, and 28 have been canceled.

Under 35 U.S.C. § 102(b), a proper rejection of a claim requires that a single prior art reference disclose each and every element of the claim. Alternatively, anticipation requires that each and every element of the claimed invention be embodied in a single prior art device or practice. For anticipation, there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. (*See, e.g., W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 220 U.S.P.Q. 303, 313 (Fed. Cir. 1983); *In re Paulsen*, 30 F.3d 1475 (Fed. Cir. 1994); *In re Spada*, 911 F.2d 705 (Fed. Cir. 1990); *Minnesota Min. & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559 (Fed. Cir. 1992); *Scripps Clinic & Res. Found. v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991). Thus, in making a rejection under 35 U.S.C. § 102, the Patent Office is burdened with establishing that the cited art teaches each and every limitation of the claims. Applicant respectfully submits that the present Office Action does not meet this burden in view of the claims as currently amended.

Currently amended independent Claim 1 recites “A composition comprising skin and glucosaminoglycan in the absence of serum.” Applicant notes that as Claims 2-3, 10-12, and 25-26 depend from Claim 1, each of these dependent claims incorporates all of the elements of currently pending Claim 1. Guienne fails to teach or disclose the composition of these claims.

Guienne is directed to investigating the effect of hyaluronic acid on the production of bovine *blastocysts* during *in vitro* maturation. (Emphasis added). Guienne discloses that *presumptive zygotes* were cultured in two different systems, one of which used hyaluronic acid as a substitute for serum. (Emphasis added).

Guienne fails to teach or disclose a composition comprising skin and glucosaminoglycan in the absence of serum as currently claimed. In fact, nowhere in Guienne is there any teaching or disclosure of skin, much less a composition comprising skin and glucosaminoglycan in the absence of serum.

For at least these reasons, Applicant respectfully submits that Guienne does not teach or disclose each and every element of Applicant's currently pending independent Claim 1. Consequently, Guienne fails to anticipate Claim 1 and dependent Claims 2-3, 10-12, and 25-26. Applicant respectfully requests that the Examiner withdraw this rejection and allow Claims 1-3, 10-12, and 25-26.

B. ALKEMADE

The Office Action rejected Claims 1-5, 7, 10-12, 25-26, and 28-29 under 35 U.S.C. § 102(b) as being anticipated by Alkemade *et al.* (1992) U.S. Patent No. 5,102,783 (herein “Alkemade”). Specifically, the Office Action stated “Alkemade *et al.* teach a composition for culturing and freezing cells (thus, preserving cells) without serum substituted by hyaluronic acid” (Office Action, p. 6). Applicant respectfully traverses this rejection to the extent that the rejection applies to the claims as amended. Applicant notes that in this Response, Claims 4-5, 7, and 28-29 have been canceled.

The proper standard for a rejection under 35 U.S.C. § 102 is set forth above. Applicant respectfully submits that the present Office Action does not meet this burden in view of the claims as currently amended.

Currently amended independent Claim 1 recites “A composition comprising skin and glucosaminoglycan in the absence of serum.” Applicant notes that as Claims 2-3, 10-12, and 25-26 depend from Claim 1, each of these dependent claims incorporates all of the elements of currently pending Claim 1. Alkemade fails to teach or disclose the composition of these claims.

Alkemade is directed to a composition “for culturing and freezing *embryos, ova* and *sperm.*” (Abstract) (Emphasis added). Each of the experiments of Alkemade focuses on storing, freezing, or incubating *mouse or bovine embryos* in media containing hyaluronic acid and the effect of hyaluronic acid on the survival of *the embryos*. (Emphasis added).

Alkemade fails to teach or disclose a composition comprising skin and glucosaminoglycan in the absence of serum as currently claimed. In fact, nowhere in Alkemade is there any teaching or disclosure of skin, much less a composition comprising skin and glucosaminoglycan in the absence of serum.

For at least these reasons, Applicant respectfully submits that Alkemade does not teach or disclose each and every element of Applicant’s currently pending independent Claim 1. Consequently, Alkemade fails to anticipate Claim 1 and dependent Claims 2-3, 10-12, and 25-26. Applicants respectfully request that the Examiner withdraw this rejection and allow Claims 1-3, 10-12, and 25-26.

C. LINDSTROM

The Office Action rejected Claims 1-3, 5, 10-12, and 25-29 under 35 U.S.C. § 102(b) as being anticipated by Lindstrom et al. (1992) European Patent Application Publication No. 0 516 901 (herein "Lindstrom"). Specifically, the Office Action stated "Lindstrom et al. teach a serum-free composition (storage solution) for enhancing preservation of *eye tissue* comprising HA." (Office Action, p. 7) (Emphasis added). Applicant respectfully traverses this rejection to the extent that the rejection applies to the claims as amended. Applicant notes that in this Response, Claims 5, 27, 28, and 29 have been canceled.

The proper standard for a rejection under 35 U.S.C. § 102 is stated above. Applicant respectfully submits that the present Office Action does not meet this burden in view of the claims as currently amended.

Currently amended independent Claim 1 recites "A composition comprising skin and glucosaminoglycan in the absence of serum." Applicant notes that as Claims 2-3, 10-12, and 25-26 depend from Claim 1, each of these dependent claims incorporates all of the elements of currently pending Claim 1. Lindstrom fails to teach or disclose the composition of these claims.

Lindstrom is directed to the "preservation of *eye tissue* in a nutritive, aqueous medical solution" (page 2, col. 1, ll. 5-7) (Emphasis added). To this end, Lindstrom explains that "cornea preservation solutions are well known" and that "those employed herein contain an aqueous nutrient and electrolyte solution, a glucosaminoglycan" (page 4, col. 8, ll. 42-45).

Lindstrom fails to teach or disclose a composition comprising skin and glucosaminoglycan in the absence of serum as currently claimed. In fact, nowhere in Lindstrom is there any teaching or disclosure of skin, much less a composition comprising skin and glucosaminoglycan in the absence of serum.

For at least these reasons, Applicant respectfully submits that Lindstrom does not teach or disclose each and every element of Applicant's currently pending independent Claim 1. Consequently, Lindstrom fails to anticipate Claim 1 and dependent Claims 2-3, 10-12, and 25-26. Applicant respectfully requests that the Examiner withdraw this rejection and allow Claims 1-3, 10-12, and 25-26.

REJECTIONS UNDER 35 U.S.C. § 103

The Office Action rejected Claims 1-5, 7, 10-12, and 25-29 under 35 U.S.C. § 103 as being obvious over Alkemade. The Office Action stated that Alkemade “teach the limitations of claims 1-5, 7, 10-12, 25, 26, 28 and 29, and thus render the claims obvious.” (Office Action, p. 8). While the Office Action acknowledged that Alkemade “do not particularly teach the cells being in sheets”, it would have been obvious to the skilled person at the time of the invention “to utilize any type of cell including those in sheets for the preservation purpose in the composition comprising HA in the absence of serum as taught be Alkemade.” (Office Action, p. 8). Applicant respectfully traverses this rejection to the extent that the rejection applies to the claims as amended. Applicant notes that in this Response, Claims 4-5, 7, 27, 28, and 29 have been canceled.

Under 35 U.S.C. § 103(a), the Patent Office bears the burden of establishing a *prima facie* case of obviousness. A *prima facie* case of obviousness requires: (1) that there be a suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings; (2) that there be a reasonable expectation of success; and (3) that the prior art reference (or references when combined) teaches or suggests all of the claim limitations. (See, e.g., M.P.E.P. § 2143). The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and cannot be based on Applicants' disclosure. (See, e.g., *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991); *In re Fine*, 87 F.2d 1071, 1074 (Fed. Cir. 1988)). Furthermore, rejections based on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be explicit analysis including some rational underpinning to support the legal conclusion of obviousness. (*K.S.R. Int'l Co. v. Teleflex, Inc.*, 550 U.S. 14 (2007) (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). If the references do not teach each of the claimed elements, then a finding of obviousness fails.

Applicant notes that the Office Action applied Alkemade in the § 103(a) rejection in the same way and for the same disclosure for which the Office Action applied Alkemade in the § 102(b) rejection. For at least the reasons discussed above with respect to the § 102(b) rejection, Alkemade fails to teach or suggest each and every element of currently amended Claim 1. Specifically, Alkemade fails to teach or disclose a composition comprising skin and glucosaminoglycan in the absence of serum as currently claimed. In fact, nowhere in Alkemade

is there any teaching or disclosure of skin, much less a composition comprising skin and glucosaminoglycan in the absence of serum. Furthermore, neither Alkemade nor the Office Action provide a clear link between the *mouse and bovine embryos* disclosed in Alkemade and the *skin* claimed by Applicant. (Emphasis added). In the absence of such a link, there is no suggestion of a composition comprising skin and glucosaminoglycan in the absence of serum as currently claimed.

Therefore, Alkemade fails to render as obvious independent Claim 1. As Claims 2-3, 10-12, and 25-26 depend from Claim 1, and “dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious” (In re Fine, 5 U.S.P.Q. 2d 1569, 1600 (Fed. Cir. 1988)), Alkemade fails to render obvious dependent Claims 2-3, 10-12, and 25-26. Applicant respectfully requests that the Examiner withdraw this rejection and allow Claims 1-3, 10-12, and 25-26.

NEW CLAIMS 30-32

With the entry of this Response, Applicant has added Claims 30-32. For at least the reasons stated above, Applicant submits that new Claims 30-32 are patentable.

CONCLUSION

The foregoing is a complete response to the Non-Final Office Action mailed August 10, 2010. Applicant respectfully submits that at least Claims 1-3, 10-12, 25-26, and 30-32 are patentable. Early and favorable consideration is solicited. Applicant files this Response solely to facilitate prosecution. As such, Applicant reserves the right to pursue claims of broader or similar scope as originally filed in a continuation application or other application after allowance of the present application.

If the Examiner believes there are other issues that can be resolved by a telephone interview, or that there are informalities that remain in the application that may be corrected by the Examiner’s amendment, a telephone call to the undersigned attorney at (678) 420-9408 is respectfully solicited.

With this Response, Applicant also submits a credit card payment in the amount of \$245, which represents the small entity fee for a two-month extension of time pursuant to 37 C.F.R. § 1.17(a)(2). Applicant submits that this is correct amount due; however, Applicant authorizes the

Commissioner to charge to Deposit Account No. 14-0629 any additional fee that may be required, or to deposit to the same account any overpayment of fees.

Respectfully submitted,

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